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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,077	10/19/2000	Ilya Ravkin	VAI 301B	7890

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PERKINS COIE LLP
P.O. BOX 2168
MENLO PARK, CA 94026

EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary*File Copy*

Application No.

09/694,077

Applicant(s)

RAVKIN ET AL.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Status of the Application

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is 703-308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Supervisory Patent Examiner, at (703) 308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restrictions

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, 18, and 20 drawn to "a chemical-library composition" comprising "a plurality of coded carriers" with "a different known chemical compound carried on each ... carrier", classified variously, for example, in class 435, DIG 22 or 34 and other classes and subclasses depending on the compounds in the library.
 - II. Claim 15 drawn to "an array" comprising "a surface" and "a plurality of spatially coded carriers", classified variously, for example, in class 435, DIG 49 or other classes and subclasses depending on the compounds attached to the carriers.
 - III. Claims 21-24 drawn to "a coded particle for use in carrying out selected chemical or biological reactions or analyses" classified variously, for example, in class 435, subclass 7.1 or class 436, subclass 501.
 - IV. Claims 27 and 28 drawn to "a composition ... of one or more different known cell populations", classified variously, for example, in class 435, DIG 22, 25, and 26 or other classes and subclasses depending on the types of cells attached to each different carrier.

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- V. Claim 29 drawn to “a microparticle for carrying and identifying one or more compounds or biological entities attached thereto”, classified variously, for example, in class 435, subclass 7.1 or class 436, subclass 501.
- VI. Claims 25 and 26 drawn to an apparatus for “detecting activity on the coded carrier of claim 21, and determining said code”, classified variously, for example, in class 359, subclass 109 or class 362, subclass 551.
- VII. Claim 30 drawn to an apparatus for “analyzing events occurring on or adjacent a microparticle containing an identifying code having at least one code viewing surface”, classified variously, for example, in class 435, DIG 45 or class 359, subclass 109.
- VIII. Claim 16 drawn to a kit described as “a plurality of separated classes of compoundless coded carriers, classified in class 435, subclass 808 and various other classes and subclasses depending on the compositions of the carriers and classes of carriers.
- IX. Claims 8 and 9 drawn to a method of making “a library of determinable chemical compounds”, classified, in class 435 and various subclasses, depending on the compositions of the compounds.
- X. Claim 17 drawn to a method for making “the composition in claim 1”, classified variously, for example, in class 435, DIG 46-49.
- XI. Claims 10-13 drawn to a method of using a chemical-library composition for “detecting one or more target molecules capable of binding specifically to one or more different, known library compounds”, classified in class 435, DIG 14 and various other classes and subclasses depending on the composition of known library compounds and target molecules screened.
- XII. Claim 14 drawn to a method of using “a plurality of said coded carriers of claim 1” for “multiplexing the detection and quantification of analytes”, classified variously, for example in class 435, DIG 14 or 15.
- XIII. Claim 19 drawn to a method of using a “plurality of sublibraries” for “detecting two or more target molecules in an analyte capable of binding specifically to two

or more known different compounds”, classified variously, for example in class 435, DIG 14 or 15.

The inventions are distinct, each from the other because:

1. Groups I-VIII represent separate and patentably distinct products because they differ in respect to their properties, their use and the methodology for making them. In the instant case, Group I claims “a chemical-library composition” that requires a “known chemical compound carried on each different-combination carrier”, which Groups I, II, IV, and VI-VIII do not claim (Groups III and V differ from Group I in other ways described below). Group II claims “an array” that requires “carriers randomly distributed upon a surface”, which Groups I and III-VIII do not claim. Group III claims “a coded particle” that requires “each of said carriers [to be] formed of N separate layers or bundled fibers ... and shape[d] ... to self-orient into a carrier holder”, which Groups I, II, and IV-VIII do not claim. Group IV claims “a composition” that requires “a different known cell population attached to each different carrier”, which Groups I-III and V-VIII do not claim. Group V claims “a microparticle” that requires “known compounds or biological entities attached to said carrier ... [to have] at least one identifying feature”, which Groups I-IV, VI-VIII do not claim. Group VI claims “an apparatus for detecting activity on the coded carriers” that requires “a carrier holder array”, which Groups I-V, VII, and VIII do not claim. Group VII claims “an apparatus for analyzing events occurring on or adjacent a microparticle” that requires “one or more fiber optic receivers”, which Groups I-VI and VIII do not claim. Group VIII claims “a kit” that requires “a plurality of separated classes of compoundless coded carriers”, which Groups I-VII do not claim. Therefore, Groups I-VIII have

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different issues regarding patentability and enablement and represent patentably distinct subject matter.

2. Groups I-VIII and Groups IX-XIII are distinct, each from the other because Groups IX-XIII represent method claims, whereas Groups I-VIII do not. However, if applicant argues that Groups IX and I or Groups X and I are related as process of making and product made, the inventions can be said to be patentably distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the library composition as claimed in Group I can be made by more than one materially different process (i.e. various combinatorial synthetic processes).

3. Furthermore, if applicant argues that Groups XI and I or XII and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed in Group I can be used by more than one materially different process (i.e. as starting materials for further library diversification).

4. Groups IX-X and Groups XI-XIII are distinct, each from the other because Groups IX-X represent methods for making a chemical-library composition, whereas Groups XI-XIII represent

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methods for using a chemical-library composition. As a result, the methods use different steps, require different reagents and/or will produce different results. Therefore, Groups IX-X have different issues regarding patentability and enablement than Groups XI-XIII and represent patentably distinct subject matter.

5. Furthermore, Group IX uses different steps, requires different reagents and/or will produce different results than Group X. In the instant case, Group X requires “bundling together ... filaments to form a fused bundle, and sectioning said fused bundle to form carriers”, which is a step that is not required by the method of Group IX. Therefore, Group IX has different issues regarding patentability and enablement than Groups X and represents patentably distinct subject matter.

6. Likewise, Groups XI-XIII require different steps, different reagents and/or will produce different results than each other and, as a result, are patentably distinct. In the instant case, Group XIII requires “partitioning the carrier library into a plurality of sublibraries”, which is an example of a step that is not required by the method of Groups XI and XIII. Furthermore, Group XI requires “detecting carriers having bound target molecules”, which is an example of a step that is not required by the method of Groups XII. Therefore, Groups XI-XIII have different issues regarding patentability and enablement and represent patentably distinct subject matter.

7. Because these inventions are distinct for the reasons given above and

- a. have acquired a separate status in the art as shown by their different classification;

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- b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
- c. have divergent subject matter, restriction for examination purposes as indicated is proper.

8. This application contains claims directed to the following patentably distinct species of the claimed inventions as set forth below.

9. If Applicant elects Group I, applicant is required to elect one species from each of the following categories:

- A) species of coded carriers,
- B) species of detectable indicia,
- C) species of known chemical compounds,
- D) species of known identifiable characteristics,
- E) species of how (the manner in which) carriers are coded, AND
- F) species of carrier layers.

Note: In addition to the general categories listed above, a *specific structure* from categories A-D must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

10. If Applicant elects Group II, applicant is required to elect one species from each of the following categories:

- A) species of surface,
- B) species of coded carriers,
- C) species of optically coding indicia,
- D) species of different chemical compounds, AND
- E) species of how (the manner in which) carriers are coded.

Note: In addition to the general categories listed above, a *specific structure* from categories B-D must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

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11. If Applicant elects Group III, applicant is required to elect one species from each of the following categories:

- A) species of coded carriers,
- B) species of detectable indicia,
- C) species of known chemical compounds,
- D) species of carrier,
- E) species of how (the manner in which) carriers are coded (e.g. color coded), AND
- F) species of carrier holders.

Note: In addition to the general categories listed above, a *specific structure* from categories A-C must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

12. If Applicant elects Group IV, applicant is required to elect one species from each of the following categories:

- A) species of coded carriers,
- B) species of detectable indicia,
- C) species of known cell population, AND
- D) species of how (the manner in which) carriers are coded.

Note: In addition to the general categories listed above, a *specific structure* from categories A and B must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

13. If Applicant elects Group V, applicant is required to elect one species from each of the following categories:

- A) species of coded carriers,
- B) species of detectable indicia,
- C) species of known chemical compounds,
- D) species of identifying features, AND
- E) species of how (the manner in which) carriers are coded (e.g. color coded).

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Note: In addition to the general categories listed above, a *specific structure* from categories A-D must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

14. If Applicant elects Group VI, applicant is required to elect one species from each of the following categories:

- A) species of coded carriers,
- B) species of holders,
- C) species of spatial code, AND
- D) species of activity.

Note: In addition to the general categories listed above, a *specific structure* from categories A-C must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

15. If Applicant elects Group VII, applicant is required to elect one species from each of the following categories:

- A) species of fiber optic receivers,
- B) species of detector,
- C) species of known coded microparticle, AND
- D) species of reader.

16. If Applicant elects Group VIII, applicant is required to elect one species from each of the following categories:

- A) species of coded carriers,
- B) species of detectable indicia, AND
- E) species of how (the manner in which) carriers are coded.

Note: In addition to the general categories listed above, a *specific structure* from categories A and B must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

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17. If Applicant elects Group IX, applicant is required to elect one species from each of the following categories:

- A) species of coded carriers,
- B) species of detectable indicia,
- C) species of reagents,
- D) species of known library compounds, AND
- E) species of how (the manner in which) carriers are coded.

Note: In addition to the general categories listed above, a *specific structure* from categories A-D must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

18. If Applicant elects Group X, applicant is required to elect one species from each of the following categories:

- A) species of coded carriers,
- B) species of detectable indicia,
- C) species of known chemical compounds, AND
- D) species of how (the manner in which) carriers are coded, AND

Note: In addition to the general categories listed above, a *specific structure* from categories A-C must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

19. If Applicant elects Group XI, applicant is required to elect one species from each of the following categories:

- A) species of coded carriers,
- B) species of detectable indicia,
- C) species of known chemical compounds,
- D) species of target molecules, AND
- E) species of how (the manner in which) carriers are coded.

Note: In addition to the general categories listed above, a *specific structure* from categories A-D must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

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20. If Applicant elects Group XII, applicant is required to elect one species from each of the following categories:

- A) species of coded carriers,
- B) species of detectable indicia,
- C) species of known chemical compounds,
- D) species of detectable reporter, AND
- E) species of how (the manner in which) carriers are coded and detected.

Note: In addition to the general categories listed above, a *specific structure* from categories A-D must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

21. If Applicant elects Group XIII, applicant is required to elect one species from each of the following categories:

- A) species of coded carriers,
- B) species of detectable indicia,
- C) species of known chemical compounds,
- D) species of target molecules,
- E) species of how (the manner in which) carriers are coded, AND
- F) species of surface.

Note: In addition to the general categories listed above, a *specific structure* from categories A-D must be elected. Furthermore, all atoms and bonds of the elected *specific structure* must be shown (including all connecting linkages) for the purposes of a search.

22. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

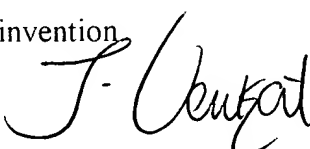
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23. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

24. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

25. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

26. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


DR. JYOTHSNA VENKAT PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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27. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

28. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D. Epperson, Ph.D. whose telephone number is (703) 308-2423. The examiner can normally be reached on Monday-Friday from 8:30 a.m. to 4:30 p.m.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Jon D. Epperson, Ph.D.

5/02/02